Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (Original) A sustained release solid dosage form, comprising the following components:

- a) a granulate comprising a uniform admixture of:
 - (i) an active ingredient selected from the group consisting of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide and a compound having the structure:

or

$$\begin{array}{c|c}
O & R_1 & O \\
N & (CH_2)n & NR_2R_3
\end{array}$$

wherein R_1 , R_2 , and R_3 are independently the same or different and are hydrogen, a C_1 - C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3; and

- (ii) a binder; and
- b) a hydroxypropylmethyl cellulose external to the granulate.

Claim 2. (Original) The solid dosage form of claim 1, wherein the solid dosage form is a tablet.

Claim 3. (Previously presented) The solid dosage form of claim 1, wherein the uniform admixture of component a) further comprises a filler.

Claim 4. (Original) The solid dosage form of claim 3, wherein the filler comprises a microcrystalline cellulose.

Claim 5. (Previously presented) The solid dosage form of claim 1, wherein the hydroxypropylmethyl cellulose comprises 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxyproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve, has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C, and has a pH in the range 5.5-8.0.

Claim 6. (Original) The solid dosage form of claim 5, wherein at least 90% of the hydroxypropylmethyl cellulose passes through a No. 100 US standard sieve.

Claim 7. (Previously presented) The solid dosage form of claim 1, further comprising as additional components a filler, a lubricant and a flow agent.

Claim 8. (Previously presented) The solid dosage form of claim 1, wherein the binder of component a)(ii) comprises hydroxypropyl cellulose.

Claim 9. (Previously presented) The solid dosage form of claim 1, further comprising a different hydroxypropylmethyl cellulose as a component.

Claim 10. (Original) The solid dosage form of claim 3, further comprising as additional components a filler, a lubricant and a flow agent.

Claim 11. (Original) The solid dosage form of claim 10, further comprising a

different hydroxypropylmethyl cellulose as a component.

Claim 12. (Previously presented) The solid dosage form of claim 9, wherein the

different hydroxypropylmethyl cellulose comprises 19-24% by weight methoxyl

substituent, 7-9% by weight hydroxypropoxyl substituent, has an apparent

viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by

rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a

concentration of 1% by weight in water at 20°C, has a pH in the range 5.5-8.0

and has a particle size distribution such that at least 99% of the

hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve.

Claim 13. (Original) The solid dosage form of claim 12, wherein at least 90% of

the hydroxypropylmethyl cellulose passes through a No. 100 US standard sieve.

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Claim 14. (Original) The solid dosage form of claim 7, wherein

the filler comprises a microcrystalline cellulose, anhydrous dicalcium phosphate, lactose, methylcellulose, carboxymethylcellulose, calcium carbonate, calcium sulfate kaolin, sodium chloride, powdered cellulose, sucrose, mannitol or a combination of two or more of the foregoing;

the lubricant comprises magnesium stearate, sodium stearyl fumarate, hydrogenated castor oil, hydrogenated soybean oil, polyethylene glycol or a combination of two or more of the foregoing; and

the flow agent comprises a colloidal fumed silica, or colloidal silicon dioxide.

Claim 15. (Original) The solid dosage form of claim 14 wherein

the filler comprises a microcyystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing;

the lubricant comprises magnesium stearate, sodium stearyl fumarate or a combination thereof; and

the flow agent comprises a colloidal fumed silica.

Claim 16. (Previously presented) The solid dosage form of claim 1 wherein the active ingredient is a compound having the structure:

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or

wherein R_1 , R_2 , and R_3 are independently the same or different and are hydrogen, a C_1 - C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3.

Claim 17. (Original) The solid dosage form of claim 16, wherein the active ingredient is N-(2-Propylpentanoyl)glycinamide.

Claim 18. (Currently Amended) A sustained release solid dosage form, comprising the following components:

- a) a granulate comprising a uniform admixture of:
 - (i) N-(2-Propylpentanoyl)glycinamide; and
 - (ii) a binder;
- b) a hydroxypropylmethyl cellulose external to the granulate; and
- c) a different hydroxypropylmethyl cellulose.

Claim 19. (Original) The solid dosage form of claim 18, wherein the solid dosage form is a tablet.

Claim 20. (Previously presented) The solid dosage form of claim 18, comprising a filler, a lubricant and a flow agent as additional components and wherein the uniform admixture of component a) further comprises a filler.

Claim 21. (Original) The solid dosage form of claim 20, wherein the binder of component a)(ii) comprises hydroxypropyl cellulose;

the filler of component a) comprises a microcrystalline cellulose;

the hydroxypropylmethyl cellulose of component b) has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100cP) by Ubbehode, at a concentration of 1% by weight in water at 20°C;

the hydroxypropylmethyl cellulose of component c) has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C;

the filler component comprises a microcrystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing,

the lubricant component comprises magnesium stearate, sodium stearyl fumarate or a combination thereof; and

the flow agent component comprises a colloidal fumed silica.

Claim 22. (Original) The solid dosage form of claim 21, comprising the following components:

- a) a uniform admixture of:
 - (i) from 50 mg/solid dosage form to 1000 mg/solid dosage form of N-(2-propylpentanoyl)glycinamide,
 - (ii) from 1 mg/solid dosage form to 100 mg/solid dosage form hydroxypropyl cellulose; and
 - (iii) from 1 mg/solid dosage form to 200 mg/solid dosage form microcrystalline cellulose;
- b) from 10 mg/solid dosage form to 300 mg/solid dosage form of hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;
- c) from 10 mg/solid dosage form to 300 mg/solid dosage form of a different hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;

- d) from 1 mg/solid dosage form to 300 mg/solid dosage form microcrystalline cellulose, anhydrous dicalcuim phosphate, lactose or a combination of two or more of the foregoing;
- e) from 0.1 mg/solid dosage form to 20 mg/solid dosage form of magnesium stearate, sodium stearyl fumarate or a combination thereof; and
- f) from 0.1 mg/solid dosage form to 15 mg/solid dosage form a colloidal fumed silica.

Claim 23. (Original) The solid dosage form of claim 21, comprising the following components:

- a) a uniform admixture of:
 - (i) from 500 mg/solid dosage form to 850 mg/solid dosage form of N-(2-propylpentanoyl)glycinamide,
 - (ii) from 25 mg/solid dosage form to 75 mg/solid dosage form hydroxypropyl cellulose; and
 - (iii) from 50 mg/solid dosage form to 150 mg/solid dosage form microcrystalline cellulose;
- b) from 100 mg/solid dosage form to 300 mg/solid dosage form of hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the

hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;

- c) from 20 mg/solid dosage form to 150 mg/solid dosage form of a different hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;
- d) from 20 mg/solid dosage form to 100 mg/solid dosage form microcrystalline cellulose, anhydrous dicalcuim phosphate, lactose or a combination of two or more of the foregoing;
- e) from 2 mg/solid dosage form to 20 mg/solid dosage form of magnesium stearate, sodium stearyl fumarate or a combination thereof; and
- f) from 0.5 mg/solid dosage form to 5 mg/solid dosage form a colloidal fumed silica, per 1 gram solid dosage form.

Claim 24. (Previously presented) The solid dosage form of claim 23, wherein at least 90% of the hydroxypropylmethyl cellulose of component b), of component c), or of both component b) and c) passes through a No. 100 US standard sieve.

Claim 25. (Original) The solid dosage form of claim 23, wherein

the hydroxypropylmethyl cellulose of component b) has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100cP) by Ubbehode, at a concentration of 1% by weight in water at 20°C; and

the hydroxypropylmethyl cellulose of component c) has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C.

Claim 26. (Original) The solid dosage form of claim 23, comprising the following components:

- a) a uniform admixture of:
 - (i) 500 mg/solid dosage form N-(2-Propylpentanoyl)glycinamide,
 - (ii) 50 mg/solid dosage form hydroxypropyl cellulose; and
 - (iii) 100 mg/solid dosage form microcrystalline cellulose;
- b) 150 mg/solid dosage form of hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;

- c) 60 mg/solid dosage form of a different hydroxypropylmethyl cellulose having 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve;
- d) 20 mg/solid dosage form lactose;
- e) 4.5 mg/solid dosage form magnesium stearate; and
- f) 1 mg/solid dosage form colloidal fumed silica.

Claim 27. (Original) The solid dosage form of claim 26, wherein at least 90% of the hydroxypropylmethyl cellulose of component b), of component c) or of both component b) and c) passes through a No. 100 US standard sieve.

Claim 28. (Original) The solid dosage form of claim 26, wherein

the hydroxypropylmethyl cellulose of component b) has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100cP) by Ubbehode, at a concentration of 1% by weight in water at 20°C; and

the hydroxypropylmethyl cellulose of component c) has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C.

Claim 29. (Original) A hard compressed tablet comprising a uniform admixture of the following components:

- a) N-(2-Propylpentanoyl)glycinamide;
- b) a hydroxypropylmethyl cellulose; and
- c) a different hydroxpropylmethyl cellulose.

Claims 30-37. (Canceled)

Claim 38. (Currently Amended) A <u>tablet</u>, composition in granulate form comprising:

- a) a granulate comprising a uniform admixture of:
 - (i) an active ingredient selected from the group consisting of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide and a compound having the structure:

$$\bigcap_{N} \bigcap_{(CH_2)n} \bigcap_{NR_2R_3}$$

or

wherein R_1 , R_2 , and R_3 are independently the same or different and are hydrogen, a C_1 - C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3; and

- (ii) a hydroxypropylmethyl cellulose; and
- b) an additional hydroxypropylmethyl cellulose external to the granulate.

Claim 39. (Currently Amended). The <u>tablet</u> composition of claim 38, wherein the active ingredient comprises a compound having the structure:

$$\begin{array}{c|c}
O & R_1 & O \\
N & (CH_2)n & NR_2R_3
\end{array}$$

or

wherein R_1 , R_2 , and R_3 are independently the same or different and are hydrogen, a C_1 - C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3.

Claim 40. (Original) The <u>tablet</u> composition of claim 38, wherein the active ingredient comprises valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium or valpromide.

Claim 41. (Cancelled)

Claim 42. (Original) The tablet of claim 41, wherein the granulate further comprises a filler.

Claim 43. (Currently Amended) The tablet of claim 41, further comprising [[a]] an additional another hydroxypropylmethyl cellulose as a component.

Claim 44. (Original) The table to of claim 41, further comprising as additional components a filler, a lubricant and a flow agent.

Claim 45. (Original) The tablet of claim 43, further comprising as additional components a filler, a lubricant and a flow agent.

Claim 46. (Cancelled)

Claim 47. (Currently Amendedd) The tablet of claim 43, wherein

the <u>another</u> hydroxypropylmethyl cellulose has 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve.

Claim 48. (Currently Amended) The tablet of claim 47, wherein at least 90% of the <u>another</u> hydroxypropylmethyl cellulose passes through a No. 100 US standard sieve.

Claim 49. (Currently Amended) The tablet of claim 47, wherein

the <u>another</u> hydroxypropyl methyl cellulose has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100cP) by Ubbehode, at a concentration of 1% by weight in water at 20°C.

Claim 50. (Currently Amended) The tablet of claim 46, wherein

the different additional another hydroxypropylmethyl cellulose has 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve.

Claim 51. (Currently Amended) The tablet of claim 50, wherein at least 90% of the <u>another</u> hydroxypropylmethyl cellulose passes through a No. 100 US standard sieve.

Claim 52. (Currently Amended) The tablet of claim 50, wherein

the different additional another hydroxypropylmethyl cellulose has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C.

Claim 53. (Original) The tablet of claim 42, wherein the filler in the granulate is a microcrystalline cellulose.

Claim 54. (Currently Amended) The tablet of claim 45, wherein

The filler comprises a microcrystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing;

The lubricant comprises magnesium stearate, sodium stearyl fumarate or a combination thereof; and

The flow agent comprises a colloidal fumed silica.

Claim 55. (Currently Amended) A sustained release tablet, comprising:

a granulate comprising a compound having the structure:

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wherein R_1 , R_2 , and R_3 are independently the same or different and are hydrogen, a C_1 - C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3; and

a hydroxypropylmethyl cellulose external to the granulate.

Claim 56. (Original) The sustained release tablet of claim 55, wherein the compound is N-(2-propylpentanoyl)glycinamide.

Claim 57. (Previously presented) A method of treating neuropathic pain in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of claim 1 in order to thereby treat the neuropathic pain in the subject.

Claim 58. (Previously presented) A method of treating a headache disorder in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of claim 1 in order to thereby treat the headache disorder in the subject.

Claim 59. (Previously presented) A method of treating a epilepsy in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of claim 1 in order to thereby treat epilepsy in the subject.

Claim 60. (Previously presented) A method of controlling seizures in a subject

suffering from epilepsy comprising administering to the subject a therapeutically

effective dose of the solid dosage form of claim 1 in order to thereby control the

seizures in the subject.

Claim 61. (Previously presented) A method of treating pain in a subject in need

of such treatment comprising administering to the subject a therapeutically

effective dose of the solid dosage form of claim 1 in order to thereby treat pain in

the subject.

Claim 62. (Previously presented) A method of pain prophylaxis in a subject in

need of such treatment comprising administering to the subject a prophylactic

dose of the solid dosage form of claim 1 in order to thereby effect pain

prophylaxis in the subject.

Claim 63. (Previously presented) A method of treating mania in bipolar disorder

in a subject in need of such treatment comprising administering to the subject a

therapeutically effective dose of the solid dosage form of claim 1 in order to

thereby treat mania in bipolar disorder in the subject.

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Claim 64. (Previously presented) A method of attenuating bipolar mood swings in a subject suffering from bipolar disorder comprising administering to the subject a therapeutically effective dose of the solid dosage form of claim 1 in order to thereby attenuate the bipolar mood swings in the subject.

Claim 65. (Currently Amended) A process for preparing the solid dosage form of claim 1, comprising the steps of:

- a) forming a granulate by admixing predetermined amounts of
 - (i) an active ingredient selected from the group consisting of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide and a compound having the structure:

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or

wherein R_1 , R_2 , and R_3 are independently the same or different and are hydrogen, a C_1 - C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3; and

- (ii) a binder;
- b) admixing the uniform mixture of step a) with a predetermined amount of a hydroxypropylmethyl cellulose; and
- c) compressing the mixture of step b) to form the tablet, wherein the hydroxypropylmethyl cellulose is external to the granulate.

Claim 66. (Original) The process of claim 65, wherein step b) further comprises admixing the uniform mixture with a predetermined amount of a different hydroxypropylmethyl cellulose.

Claim 67. (Original) The process of claim 66, wherein step b) further comprises admixing the uniform mixture with predetermined amounts of a filler, a lubricant and a flow agent.

Claim 68. (Original) The process of claim 67, wherein the flow agent comprises colloidal fumed silica.

Claim 69. (Original) The process of claim 67, wherein the filler comprises microcrystalline cellulose, anhydrous dicalcium phosphate, lactose of a combination of two or more of the foregoing.

Claim 70. (Original) The process of claim 69, wherein the filler comprises lactose.

Claim 71. (Original) The process of claim 67, wherein the lubricant comprises magnesium stearate or sodium stearyl fumarate or a combination thereof.

Claim 72. (Original) The process of claim 71, wherein the lubricant comprises magnesium stearate.

Claim 73. (Original) the process of claim 66, wherein

each hydroxypropylmethyl cellulose of step b) has 19%-24% by weight methoxyl substituent, 7%-12% by weight hydroxylproproxyl substituent and has a particle size distribution such that at least 99% of the hydroxypropylmethyl cellulose passes through a No. 40 US standard sieve.

Claim 74. (Original) The process of claim 73, wherein at least 90% of the hydroxypropylmethyl cellulose passes through a No. 100 US standard sieve.

Claim 75. (Original) The process of claim 73, wherein

the first hydroxypropylmethyl cellulose has an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100cP) by Ubbehode, at a concentration of 1% by weight in water at 20°C; and

the second hydroxypropylmethyl cellulose has an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C.

Claim 76. (Original) A process for preparing the hard compressed tablet of claim 29 comprising the steps of:

- a) admixing predetermined amounts of N-(2-Propylpentanoyl)glycinamide, hydroxypropylmethyl cellulose, and a different hydroxypropylmethyl cellulose, and
- b) compressing the mixture of step a) to form the hard compressed tablet.

Claims 77-81. (Canceled)

Claim 82. (Original) A process for preparing the composition in granulate form of claim 38, comprising granulating a predetermined amount of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalporex sodium, valpromide or a compound having the structure:

$$\bigcap_{N} \bigcap_{N} \bigcap_{NR_{2}R_{3}} \bigcap_{NR_{2}R_{3}}$$

wherein R_1 , R_2 , and R_3 are independently the same or different and are hydrogen, a C_1 - C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3, and a predetermined amount of hydroxypropyl cellulose to form the composition in granulate form.

Claim 83. (Original) A process for preparing a sustained release tablet comprising the steps of:

- a) admixing the granules of claim 38 with predetermined amounts of a hydroxypropylmethyl cellulose; and
- b) compressing the mixture of step a) to form the tablet.

Claim 84. (Original) The process of claim 83, wherein step a) further comprises admixing the granules with a predetermined amount of each of a different hydroxypropylmethyl cellulose, a filler, a lubricant and a flow agent.

Claim 85. (Original) The process of claim 84, wherein the flow agent comprises colloidal fumed silica.

Claim 86. (Original) The process of claim 84, wherein the filler comprises microcrystalline cellulose, anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing.

Claim 87. (Original) The process of claim 86, wherein the filler is lactose.

Claim 88. (Original) The process of claim 84, wherein the lubricant comprises magnesium stearate or sodium stearyl fumarate or a combination thereof.

Claim 89. (Original) The process of claim 88, wherein the lubricant comprises magnesium stearate.

Claim 90. (Original) The process of claim 83, comprising the steps of:

- with a) admixing the granules predetermined amounts of hydroxypropyl methyl cellulose having an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C, and hydroxypropyl methyl cellulose having an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C; and
- b) compressing the mixture of step a) to form the tablet.

Claim 91. (Original) The process of claim 90, wherein step a) further comprises admixing the granules with predetermined amounts of a flow agent, a filler, and a lubricant.

Claim 92. (Original) The process of claim 91 comprising the steps of

a) admixing the granules with

a predetermined amount of hydroxypropyl methyl cellulose with an apparent viscosity of 78-117 millipascal-seconds (nominal value 98 mPa.s) by rotation and 80-120 cP (nominal value 100 cP) by Ubbelhode, at a concentration of 1% by weight in water at 20°C which results in tablets containing 150 mg/tablet;

a predetermined amount of hydroxypropyl methyl cellulose with an apparent viscosity of 6,138-9,030 millipascal-seconds (nominal value 7382 mPa.s) by rotation and 11,250-21,000 cP (nominal value 15,000 cP) by Ubbelhode at a concentration of 1% by weight in water at 20°C which results in tablets containing 60 mg/tablet;

a predetermined amount of lactose which results in tablets containing 20 mg/tablet;

a predetermined amount of magnesium stearate which results in tablets containing 4.5 mg/tablet; and

a predetermined amount of colloidal fumed silica which results in tablets containing 1 mg/tablet; and

b) compressing the mixture of step a) to form the tablet.

Claims 93-107. (Canceled)

Claim 108. (Currently Amended) A controlled release oral unit dose composition, comprising:

<u>a granulate comprising</u> N-(2-propylpentanoyl)glycinamide and at least one pharmaceutically acceptable carrier; and

a hydroxypropylmethyl cellulose external to the granulate,

wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl)glycinamide between 4 and 24 hours after ingestion of a single oral unit dose.

Claim 109. (Original) The controlled release oral unit does composition of claim 108, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl)glycinamide between 4 and 12 hours after ingestion of a single oral unit dose.

Claim 110. (Original) The controlled release oral unit does composition of claim 109, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl)glycinamide between 6 and 12 hours after ingestion of a single oral unit dose.

Claim 111. (Original) The controlled release oral unit does composition of claim 110, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl)glycinamide between 6 and 8 hours after ingestion of a single oral unit dose.

Claim 112. (Original) The controlled release oral unit does composition of claim 108, wherein the peak blood plasma level of N-(2-propylpentanoyl)glycinamide is from 0.5 micrograms/ml to 16 micrograms/ml per a 1000 mg dose of N-(2-propylpentanoyl)glycinamide in the composition.

Claim 113. (Original) The controlled release oral unit does composition of claim 108, wherein the peak blood plasma level of N-(2-propylpentanoyl)glycinamide is from 0.5 µg/ml to 1.7 µg/ml per a 1000 mg dose of N-(2-propylpentanoyl)glycinamide in the composition.

Claim 114. (Original) A controlled release oral unit does composition comprising N-(2-propylpentanoyl)glycinamide and a pharmaceutically acceptable carrier, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl)glycinamide is from 0.5 μg/ml to 16 μg/ml per a 1000 mg dose of N-(2-propylpentanoyl)glycinamide in the composition.

Claim 115. (Currently Amended) A controlled release oral unit dose composition, comprising:

<u>a granulate comprising</u> N-(2-propylpentanoyl)glycinamide and a pharmaceutically acceptable carrier; and

a hydroxypropylmethyl cellulose external to the granulate, wherein the composition when orally ingested by a human subject, induces a peak blood plasma level of N-(2-propylpentanoyl)glycinamide is from 0.5 μg/ml to 1.7 μg/ml per a 1000 mg dose of N-(2-propylpentanoyl)glycinamide in the composition.

Claim 116. (Currently amended) A method of inducing in a human subject a peak blood plasma level of N-(2-propylpentanoyl)glycinamide between 4 and 24 hours after administration of N-(2-propylpentanoyl)glycinamide, comprising:

administering to the human subject a controlled release oral unit dose composition, the controlled release oral unit does composition, comprising

<u>a granulate comprising</u> N-(2-propylpentanoyl)glycinamide and at least one pharmaceutically acceptable carrier; <u>and</u>

a hydroxypropylmethyl cellulose external to the granulate,

which wherein the controlled release oral unit does composition induces a peak blood plasma level of N-(2-propylpentanoyl)glycinamide between 4 and 24 hours after administration of a single oral unit dose.

Claim 117. (Original) The method of claim 116, wherein the peak blood plasma

level of N-(2-propylpentanoyl)glycinamide occurs between 4 and 12 hours after

administration.

Claim 118. (Original) The method of claim 116, wherein the peak blood plasma

level of N-(2-propylpentanoyl)glycinamide is 0.5 μg/ml to 16 μg/ml per 1000 mg

dose of N-(2-propylpentanoyl)glycinamide in the composition.

Claim 119. (Currently Amended) The method of claim 116, wherein the

administration to the human subject of a controlled release oral unit dose

composition comprising N-(2-propylpentanoyl)glycinamide and at least one

pharmaceutically acceptable carrier induces a peak blood plasma level of N-(2-

propylpentanoyl)glycineglycinamide in the human subject from 0.5 µg/ml to 1.7

µg/ml upon administration of a single 1000 mg dose of N-(2-

propylpentanoyl)glycinamide.

Claim 120. (Canceled)

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